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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,941	03/11/2004	Martha G. Welch	19240.477 US2	8041

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
10/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/799,941	WELCH ET AL.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,17 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2009 has been entered.

Response to Amendment/Arguments

Applicant's amendments and arguments filed July 22, 2009 are acknowledged and have been fully considered. Applicant's amendments merely adjust word order, however have no substantive effect on the claimed subject matter.

The declaration filed on July 22, 2009 under 37 CFR 1.131 has been considered, but is ineffective to overcome the Hollander (US 2006/0105939 A1) reference or Welch. Applicant's affidavit now indicates that reduction to practice occurred "at least prior to October 3, 2002", however this has already been established by Applicant in the two previous declarations, which clearly stated reduction to practice occurred "at least prior to August 17, 2001." Thus, it is apparent that applicant had reduced it prior to October 3, 2002, having already declared it had occurred at least 14 months earlier in each of the previous declarations. In the previous declarations Applicant provided a statement that the lab notes predate August 17, 2001, however the instant Application was filed March 11, 2004. Again, as before, there is no evidence of diligence between the earliest date of asserted conception (prior to 8/17/01) and the date of filing (3/11/04). Additionally, the provisional application (60/518,389) does not show diligence during

the time in question, as the priority document does not provide any disclosure of the instantly claimed composition of oxytocin with secretin, and assuming *arguendo* that such disclosure is present, it was filed more than two years after the earliest date Applicant is attempting to antedate. Furthermore, it is noted that Applicant's 'conception' in the previous declarations is equivalent to 'reduction to practice' in that Applicant made the compositions now claimed.

Thus, the rejections are maintained below for the reasons of record.

Applicant is reminded that, as previously indicated, the disclosure of the prior-filed application, Application No. 60/518,389, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, there is no disclosure of the instantly claimed combination therapeutic of oxytocin with secretin.

Thus, the priority date afforded to the claims is the instant filing date of March 11, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by WELCH (Reference CZ; PTO-1449 5/29/07).

Welch teaches administration of S/OT composition (45-90 μg) iv or ip by Alzet pump. The pump constitutes a kit comprising the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

> such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8, 17 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over HOLLANDER in view of NIH News Alert, SWAIN and PIERCE, for the reasons of record and those set forth below.

The instant claims are drawn to compositions of OT/S and a kit thereof, optionally with a protease inhibitor.

As stated previously, *In re Kerkhoven* is applicable as it is the combination of two compounds useful for the same purpose- treating autism- which are combined to make a third composition for treating autism which would flow logically from the teachings in the art.

Hollander teaches treating autism with oxytocin (claim 1) and that, "Agents suitable for use in combination therapy are any chemical compound or treatment method useful to patients with disorders associated with repetitive behaviors…" (paragraph [0046]).

NIH News Alert teaches treating autism with secretin (e.g. page 2, citing Horvath, et al.).

Swain teaches that packaging of pharmaceuticals can add to the 'bottom line' by reducing theft, counterfeiting, increasing shelf life, and improve patient compliance (page 1 of 4).

PIERCE teaches that protease inhibitors are added to protein solutions to lengthen shelf life (e.g. Table 2, page 2) by preventing cleavage of proteins.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." Thus, because both oxytocin and secretin have been taught in the prior art as useful for treating autism, it would have been obvious to have combined the two for making a composition for the same purpose.

With regards to the kit, the examiner has interpreted 'kit' broadly to include packaging for sale. It would have been obvious at the time of the invention to have packaged the pharmaceutical composition in any packaging for the benefit of reducing theft, reducing counterfeiting and increasing shelf life of the compound, as well as for the benefit of product recognition during sales of the product. One would have been motivated to have packaged the pharmaceutical for the benefit of, but not limited to, increasing shelf life of the compound and to increase the product visibility. One would have had a reasonable expectation for success in packaging the pharmaceutical in order to prolong the shelf life, as packaging pharmaceuticals is widely practiced in the formulary arts in order to generate sales.

Furthermore, it would have been obvious to have added into the composition and/or kit a protease inhibitor to prevent protein degradation/cleavage during storage to increase the shelf life. One would have been motivated to have added a protease inhibitor to the composition/kit because oxytocin and secretin are both peptide compounds, susceptible to proteolysis, and to increase the shelf life of the peptides in the composition. One would have had a reasonable expectation for success in making the composition/kit with a protease inhibitor as PIERCE

teaches protease inhibitors are added to prevent proteolytic cleavage of peptides during storage and to increase the shelf life.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654